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The minimal clinically important difference for the Gait Profile Score

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ABSTRACT

The minimally clinically important difference (MCID) is an important concept for interpreting the results of clinical research. This paper proposes a rationale for defining an MCID for the Gait Profile Score (GPS) based on an analysis of the difference in median GPS for children classified at different levels of the Functional Assessment Questionnaire. A strong linear correlation between median score and FAQ level was found. An MCID of 1.6° is therefore suggested, reflecting the mean difference between adjacent FAQ levels. Comparison of this value with (i) the standard deviation of GPS from typically developing children (1.4°) and (ii) the percentage of the difference between the median GPS for each FAQ level and that for typically developing children offers further support to suggest that 1.6° is an appropriate figure.

1. Introduction

There is an increasing emphasis in clinical research into establishing whether outcomes are clinically meaningful as well as statistically significant. The concept of minimal clinical important difference [MCID [1]] is widely accepted but there is little consensus on precise definitions [2,3]. The range of methods has been divided into *anchor based methods*, which compare a new measure to other measures of clinical evidence, and *distribution based methods* which are based on its statistical or psychometric properties [3]. Both have limitations, anchor based methods, in validating one measure on the basis of another, have the potential to be "circular in logic and fraught with potential bias" [2]. Distribution based methods "cannot address the question of clinical importance, which is central to the concept of MCID" [2].

None of the existing measures of gait quality [4–7] have had an MCID defined. Oeffinger et al. [8] reported a six year multi-centre study to define MCID for range of measures of walking function but did not include any gait quality indices. The Gait Profile Score [GPS [4,5]] represents the root mean square (RMS) difference between a particular gait trial and averaged data from people with no gait pathology. It has an advantage over the other indices as it is comprised of a number of gait variable scores (GVSs) representing an equivalent RMS difference for different kinematic variables. These can be displayed as a bar chart known as the Movement Analysis Profile (MAP). The aim of this paper is thus to define an MCID for the GPS.

The *cross-sectional approach* is an anchor based method that compares groups that are different in terms of a clinically relevant disease related criterion [3]. Within clinical gait analysis two such criterion measures of functional mobility are widely used. The Functional Assessment Questionnaire [FAQ [9]] is a 10 point scale (6–10 describe functional walkers with 10 being most able) which was designed specifically to be used as an outcome measure. The Gross Motor Function Classification System [GMFCS [10,11]] is designed for children with cerebral palsy (CP) with five levels (functional walkers are classified within levels I–III, with I being the most able). Both scales were derived by clinicians to define groups of children whose physical function is clinically different and both were developed independently of any consideration of instrumented gait analysis (IGA). The GMFCS was derived using a Delphi process involving 48 clinicians from a range of backgrounds [10]. It is more difficult to establish the construct validity of the FAQ from the original publication [9] but this has now been cited over 100 times reflecting widespread acceptance within the clinical research community (and thus high face validity). They

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thus appear ideal candidates for defining MCID for a single gait index defined from IGA. The FAQ is not restricted to any particular age group or disease condition and the larger number of five categories for functional walkers allow for greater discrimination across the wide spectrum of walking abilities than the three levels of the GMFCS that represent functional walking ability. For this reason it will be used as the primary measure for determining MCID of the GPS. The GMFCS is probably more widely accepted and has been more rigorously validated for children with CP, it is a classification system rather than an outcome measure but the different levels still represent differences in physical function. Analysis of differences in GPS between GMFCS levels will therefore be presented as a secondary analysis to provide further justification for the MCID determined from FAQ data.

Whilst the focus of this study will be on this cross-sectional approach the results will be discussed in the context of alternate methods. *Sample variation* [3] is a distribution based approach defining MCID in terms of a measure's variability within a particular sample population. Selection of an appropriate reference population is dependent on how clinicians typically use the data within clinical reasoning and practice. Almost all clinical gait analysis compares data from individuals against control data from a reference population without gait pathology [12]. The standard deviation of this population thus seems an obvious parameter against which to consider any proposed MCID.

Another approach [13] is to define a threshold for MCID as an appropriate percentage of a score of disease severity. A consortium working with pain suggested a generic 30% reduction from baseline as appropriate [13]. Whilst this approach appears sensible, subjective semi-qualitative pain scores are quite different from objective quantitative measures such as the GPS and a 30% reduction may be too conservative. Schwartz et al. [14] suggested a threshold of 10% improvement for a range of measures of gait pathology. Extending this approach to the GPS would have to be modified as the healthy population has a non-zero GPS.

2. Methods

The GPS [5] is based upon a number of gait variable scores (GVS) each of which is the root mean square difference between a specific time normalized gait variable and the mean data from some reference population calculated across the gait cycle. Thus if $x_{i,t}$ is the value of gait variable i calculated at a specific point in the gait cycle t, and $\bar{x}^{\mathrm{ref}}_{i,T}$ is the mean value of that variable at the same point in the gait cycle for the reference population then the ith gait variable score is given by:

$$\mathrm{GVS}_i = \frac{1}{T}\sum_{t=1}^{T}(x_{i,t} - \bar{x}^{\mathrm{ref}}_{i,t})^2$$

where T is the number of instants into which the gait cycle has been divided. The GPS is then the RMS average of the GVS variables:

$$\mathrm{GPS} = \frac{1}{N}\sum_{i=1}^{N}\mathrm{GVS}_i^2$$

The overall GPS proposed in the original paper [5] is based upon 15 clinically important kinematic variables (pelvic tilt, obliquity and rotation of the left side and hip flexion, abduction, internal rotation, knee flexion, dorsiflexion and foot progression for left and right sides). In this analysis a GPS score for each side was used based on all nine GVS for that side.

The dataset previously reported by Baker et al. [5] in the original description of the GPS forms the basis of this analysis. This included all 407 children (under the age of 18; mean age 12 (SD, 3)) who attended a tertiary paediatric hospital for gait analysis in 2005, 2006 and 2007, and a sample of convenience of 38 typically developing (TD) children (mean age 11 (SD 3)). The children with gait pathology included 271 with CP, 88 with general orthopaedic conditions, and 48 with other neurological conditions. Gait data was captured with a VICON system and processed using their PlugIn Gait software (Vicon, Oxford, UK) and uploaded to Gaitabase software [15]. The first gait cycle from each of three separate trials described in the original publication [5] was selected for each child and the GPS calculated for each leg. FAQ [9] and GMFCS level [10] was assigned by a each gait assessment. The FAQ was selected by the child's parents from a list with the descriptors proposed by Novacheck et al. [9]. The GMFCS was assigned by a senior clinical physiotherapist in consultation with the child and his or her parents. Given that the distribution of the GPS is known to be skewed within each FAQ and GMFCS level [5] but the log transform is normally distributed, the median and lower and upper quartile scores were estimated by fitting a Gaussian distribution to the log transformed GPS following Baker et al. [5]. Whilst a strong relationship between GPS and both FAQ and GMFCS is expected, there is no reason, *a priori*, to assume a linear (or any other) correlation. The rationale for choosing a particular value of MCID is thus considered a part of Section 4.

The FAQ and GMFCS are classifications or measures of overall function and are not necessarily correlated to the function of any particular joint. It is thus not sensible to use this approach to define MCIDs for each of the GVS constituting the MAP. The corresponding correlation between FAQ level and the GVS, however, is of general interest and, as a by-product of this analysis, is also included.

3. Results

Three hundred and eighty two children were recorded as having a FAQ level which range from 6 to 10 and 268 of those with cerebral palsy as having a GMFCS level ranging from I to III. Table 1 records the numbers in each of these groups, their median and inter quartile range GPS (also plotted in Fig. 1). The gradient of the line of regression (Fig. 1) is taken as a measure of the average difference of GPS median score between adjacent levels and is 1.6° (s.e. 0.2°) for FAQ and 2.9° (s.e. 0.4°) for GMFCS. The very high r^2 values are a consequence of performing the regression on the median values, corresponding values including each child as a separate data point are $r^2 = 0.27$ (FAQ) and 0.30 (GMFCS). The GPS for the TD group is normally distributed with a mean value of 5.3° and standard deviation of 1.4° (median and IQR are plotted in Figs. 1 and 2 for consistency with the patient data). Fig. 2 represents the correlation of the individual GVS components of the MAP with FAQ.

4. Discussion

The linearity of the correlation between GPS median values and both FAQ and GMFCS levels is quite remarkable given that definitions of both levels have been developed independently of each other and prior to the conception of the GPS. (Even more remarkably inclusion, of the TD group as an extension of the classification system has little effect on the r^2 values.) This provides a strong rationale for taking the gradient of the regression line with FAQ score as indicative of an MCID for GPS giving MCID = 1.6°. A value of 2.9° would have resulted if differences between GMFCS levels had been used. Given that classifying motor function into

Table 1
Median and inter-quartile range (IQR) estimates by FAQ and GMFCS level. The final column in both tables displays an MCID of 1.6° as a % of the difference in median scores between children in each FAQ or GMFCS level and TD children (see Section 4).

FAQ level	Number	Median	IQR	1.6° as % difference from TD	GMFCS level	Number	Median	IQR	1.6° as % difference from TD
6	29	14.3°	4.7°	17%	III	52	13.9°	4.3°	18%
7	48	11.4°	4.8°	25%	II	142	10.4°	4.2°	30%
8	89	10.9°	4.6°	28%	I	74	8.1°	2.4°	54%
9	125	9.0°	3.5°	41%					
10	91	7.6°	3.3°	64%	TD	38	5.1°	1.8°	

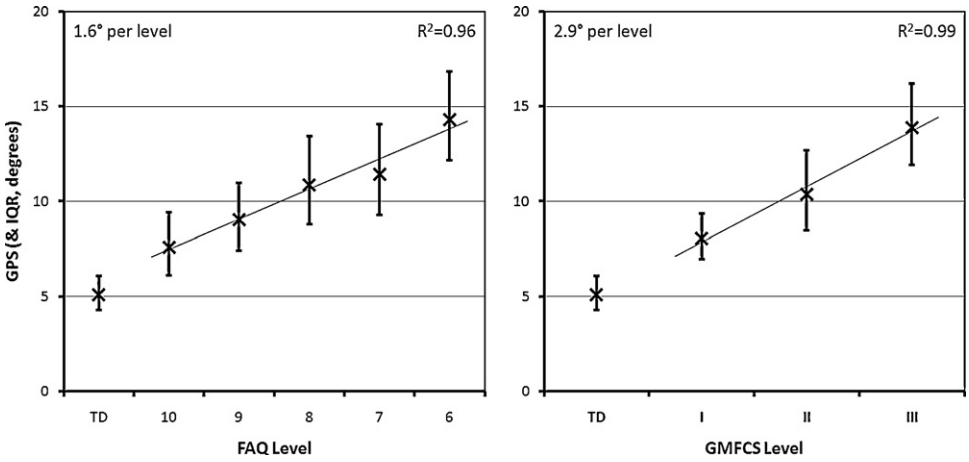

Fig. 1. Median and inter-quartile range for GPS plotted against FAQ and GMFCS levels.

just three levels across the spectrum of ambulant children with CP is rather crude and that MCID is a measure of *minimal* clinically important difference this adds further justification to the use of a somewhat smaller value (1.6°) for MCID.

The standard deviation in GPS for the TD group is 1.4° so an MCID of 1.6° is just over one standard deviation. This appears appropriate given that clinicians typically interpret clinical gait data with individual traces plotted against a band of ±1 SD. Expressing an MCID of 1.6° as a percentage of the difference from the TD group (following Dworkin et al. [13]) clearly depends on level (Table 1). This exceeds the 30% threshold proposed by Dworkin et al. [13] for FAQ levels 9 and 10 and GMFCS levels I and II, and the 10% threshold value proposed by Schwartz et al. [14] for all groups. Given, as argued in the Introduction, that the 30% threshold is perhaps too conservative for a quantitative outcome measure such as GPS is too conservative then an MCID of 1.6° thus seems appropriate.

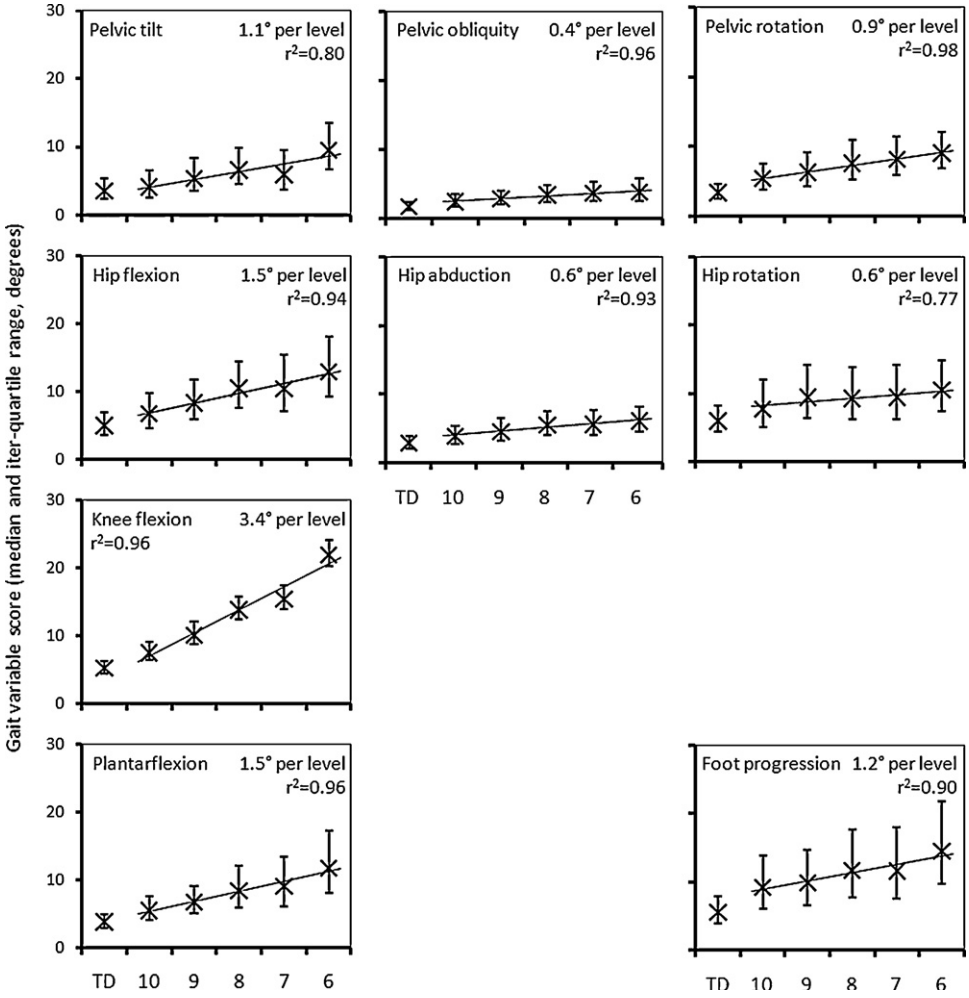

Fig. 2. Variation of gait variable score (components of the Movement Analysis Profile) with FAQ level.

On the other hand, 1.6° appears a small quantity in absolute terms and is only 40% of average standard deviation across relevant kinematic parameters in the TD group (closely approximated by the median GPS of 5.1°). To understand how this can describe changes of major clinical significance it is important to understand the relationship with the individual GVSs (Fig. 2). There is considerable variation in the average differences of different GVSs between adjacent FAQ levels. Knee flexion varies by 3.4° per level whereas hip rotation, abduction and pelvic obliquity only vary by around 0.5°. A change in GPS of 1.6° is thus unlikely to represent a uniform change of just 1.6° across all gait parameters but is more likely to represent a mix of much bigger changes in some of the constituents of the MAP and much smaller changes in others. Similar factors apply across the gait cycle with substantial changes at critical phases within the gait cycle often being balanced by more modest changes at others.

The GPS has only recently been defined so there are few reports of its use in clinical research. Thomason et al. [16] compared outcomes from Single Event Multi-Level Surgery for children with diplegia over twelve months with those of no surgery and a programme of progressive resistive strength training. The difference in the primary outcome measure of GPS at 12 months was 5.4°. A variety of outcome measures at 12 and 24 months across the spectrum of impairments, activities, and participation suggest clinical improvements considerably above a minimally clinically important difference and provide additional longitudinal justification [3] for an MCID of 1.6°. Despite these marked improvements in walking only three of the patients reported in this study (16%) would have been classified as in a different GMFCS level after surgery. This confirms that basing MCID on the difference between FAQ may be a preferred approach, with GMFCS levels representing an overly conservative method.

Analysing the GVS that forms the MAP does not allow definition of an MCID for individual GVS (a measure of function at joint level would be a pre-requisite for this), but the data is informative. All GVS show a linear relationship with FAQ with a minimum r^2 value of 0.77 for hip rotation. The gradient of the regression lines varies significantly though. The GVS for knee flexion increases by 3.4° per FAQ level which is over twice the gradient of the next ranked score. The other sagittal plane variables (pelvic tilt, 1.1°; hip flexion, 1.5°; plantarflexion 1.5°) and foot progression (1.2°) rank next with pelvic obliquity and rotation and hip obliquity and rotation showing a change of less than 1° per FAQ level. This suggests that the single most important determinant of GPS in the children included in this study was knee flexion angle.

It is important to emphasize again that the MCID is a *minimal* clinically important difference. Whether a change equivalent to MCID is sufficient to justify any particular intervention will depend on the nature of the intervention, and its associated benefit relative to cost, burden and risk. It might thus be argued that changes greater than the MCID are required to justify complex, expensive and demanding interventions such as single event multi-level surgery. It should also be remembered that the MCID for the GPS which reflects overall quality may not be sensitive to focal interventions such as Botulinum toxin which might have important local effects. Definition of an MCID for the individual GVS would be required for this but is beyond the scope of this paper.

It should be noted that the GPS is only a measure of gait quality during straight line walking on a clear level surface within a gait analysis laboratory. Other outcome measures would be required to establish whether gait function, particularly in more real-world environments, has improved as the result of a particular intervention. Gait speed is not correlated with GPS [5] and it is recommended that self-selected walking speed be reported in addition to GPS for clinical studies.

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Conflict of interest statement

None.

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